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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,662	01/18/2002	Gustavo C. Rodriguez	31140B	3102

7590 10/26/2004  
Raymond N. Nimrod  
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glencoe, IL 60022

EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/051,662	<b>Applicant(s)</b> RODRIGUEZ ET AL.	
	<b>Examiner</b> Rebecca Cook	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-38 and 40-73 is/are pending in the application.
- 4a) Of the above claim(s) 40-44, 47, 48, 50-54, 58, 60-64 and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-38, 45, 46, 49, 55-57, 59, 65-71 and 73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/31/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Election/Restrictions**

Claims 35-38, 45-46, 49, 55-57, 59, 65-71 and 73 are being examined as reading on 1,25-dihydroxyvitamin D<sub>3</sub> and norethindrone, which were elected in the Paper of June 26, 2003. Claims 40-44, 47-48, 50-54, 58, 60-64 and 72 have been withdrawn as not reading on the elected invention.

### **Claim Objections**

Claims 45-46 and 49 are objected to, since they are drawn to a composition, but the intent appears to be to recite a method of use.

Applicant is advised that should claim 35 be found allowable, claims 49 and 59 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 45 be found allowable, claim 55 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Applicant is advised that should claim 46 be found allowable, claim 56 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicants argue that said claims are not duplicative, since one set of claims is directed to a dingle unit dosage that is not limited to a method of use while the second and third set are limited to contraceptive compositions and hormone replacement therapy. This is not persuasive, since intended use does not impart patentability to a composition claim.

#### **Claim Rejections - 35 USC § 112**

Claims 35-38, 45-46, 49, 55-57, 59, 65-71 and 73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "appropriate" doses (specification, page 15) of 1,25-dihydroxyvitamin D<sub>3</sub> does not reasonably provide enablement for any and all doses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Goodman and Gilman (pages 1584-1587) disclose that some of the doses disclosed in the specification and recited in the claims cause Vitamin D toxicity.

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Claims 36-38, 46, 49, 55-57, 59, 65-71 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-38, 46, 49, 55-57, 59, 65-71 and 73 are confusing to the extent that they read on estranes and gonanes, since it is not seen that estranes or gonanes are progestin compounds. Hackh's Chemical Dictionary defines gonane as the steroid parent structure. Goodman and Gilman disclose that estranes (estrogens) are distinct from progestins.

There is no antecedent basis in claim 67 for the amounts of 1,25-dihydroxyvitamin D<sub>3</sub> recited in claims 68 and 69, since claim 67 recites a dosage equivalent to 4000 IU and the amounts recited in claims 68 and 69 are greater than 400 IU.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-38, 45-46, 49, 55-57, 59, 65-71 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Need et al. Need (Page 276, Table I, Fig. 2) discloses a composition comprising 1,25-dihydroxyvitamin D<sub>3</sub> and norethindrone.

Some of the claims appear to distinguish over Need in reciting amounts and intended use. However, these do not impart patentability to a composition, since if a

composition is physically the same it must have the same properties. *In re Spada*, 15 USPQ2d 1655, *In re Best* 195 USPQ 430.

Applicants argue that need does not teach single unit dosage of progestin and Vitamin D. This is not persuasive. No distinction is seen in a unit dose formulation, since it is well-known in the pharmaceutical art.

Applicants agree that the second and third set of claims are directed to contraceptively effective compositions and hormone replacement therapy, respectively, which are not disclosed by Need. This is not persuasive, since intended use does not impart patentability to a composition claim.

The Declaration under CFR 1.132 by Dr. Rodriguez filed on September 2, 2004 has been considered but is not persuasive, since it is directed to the unobviousness of combining progestin and Vitamin D for a method of use and the instant rejection is made under 35 USC 102.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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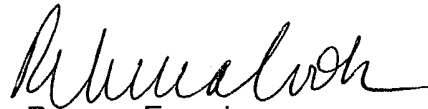
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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook

A handwritten signature in black ink, appearing to read 'Rebecca Cook', written in a cursive style.

Primary Examiner  
Art Unit 1614

October 20, 2004